Approved for use through 03/31/2007, OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE to a collection of information unless it contains a valid OMB control number.

Sub	stitute for form 1449/PTO			Complete if Known			
			Application Number	10/574,994			
IN	FORMATIO	פות וא	CLOSUDE	Filing Date	October 5, 2004 (I.A.)		
				First Named Inventor	Betty A. Diamond		
S	TATEMENT			Art Unit	to be determined		
	(Use as many si	neets as n	ecessary)	Examiner Name	to be determined		
Sheet	1 1	of	4	Attorney Docket Number	96700/1120		

		·	U. S. PATENT D		
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
		US-			
,		US-			
		US-			
		US-			
-		US-			
		US-		10-11-11-11-11-11-11-11-11-11-11-11-11-1	
		US-			
		US-			-
		US-			
		US-		***	

		FORE	IGN PATENT DOCU	MENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ^{3 -} Number ^{4 -} Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T⁵
				•		
				-		

Examiner Signature	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁸ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE Application Number 10/574,994 Filing Date October 5, 2004	Complete if Known				
Substitut	e for form 1449/PTO			Application Number	10/574,994
INFO	DRMATIO	N DIS	CLOSURE	Filing Date	October 5, 2004 (I.A.)
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Betty A. Diamond
	## ## ## ## ## ## ## ## ## ## ## ## ##			Art Unit	to be determined
	(Use as many sh	ieets as ne	ecessary)	Examiner Name	to be determined
Sheet	2	of	4	Attorney Docket Number	96700/1120

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
-	1	ABDEL-RAHMAN A. et al., "Disruption of the Blood-Brain Barrier and Neuronal Cell Death in Cingulate Cortex, Dentate Gyrus, Thalamus, and Hypothalamus in a Rat Model of Gulf-War Syndrome"; Neurobiology of Disease, 2002, Vol. 10, No. 3, pp 306-26.	
_	2	ACR AD HOC COMMITTEE ON NEUROPSYCHIATRIC LUPUS NOMENCLATURE, "The American College of Rheumatology Nomenclature and Case Definitions for Neuropsychiatric Lupus Syndromes"; Arthritis & Rheumatism, 1999, Vol. 42, No. 4, pp 599-608.	
	3	BREY R.L. et al., "Neuropsychiatric syndromes in lupus - Prevalence using standardized definitions"; Neurology, 2002, Vol. 58, No. 9, pp 1214-20.	
	4	DEGIORGIO L.A. et al., "A subset of lupus anti-DNA antibodies cross-reacts with the NR2 glutamate receptor in systemic lupus erythematosus"; Nature Medicine, 2001, Vol. 7, No. 11, pp. 1189-93	
	5	DELLALIBERA-JOVILIANO R. et al., "Kinins and Cytokines in Plasma and Cerebrospinal Fluid of Patients with Neuropsychiatric Lupus"; The Journal of Rheumatology, 2003, Vol. 30, No. 3, pp 485-92.	
	6	DENBURG S.D. and DENBURG J.A., "Cognititve Dysfunction in Systemic Lupus Erythematosus"; in Systemic Lupus Erythematosus, Third Edition, Robert G. Lahita, Editor, Academic Press, San Diego, CA, 1999, pp 611-29.	
	7	ELKON K.B. et al., "Antiribosomal Antibodies in Systemic Lupus Erythematosus"; Rheumatic Disease Clinics of North America, 1992, Vol. 18, No. 2, pp 377-90.	
	8	ESPOSITO P. et al., "Corticotropin-Releasing hormone and Brain Mast Cells Regulate Blood-Brain-Barrier Permeability Induced by Acute Stress"; The Journal of Pharmacology and Experimental Therapeutics, 2002, Vol. 303, No. 3, pp 1061-66.	
	9	FRIEDMAN A. et al., "Pyridostigmine brain penetration under stress enhances neuronal excitability and induces early immediate transcriptional response"; Nature Medicine, 1996, Vol. 2, No. 12, pp 1382-85.	
	10	GAYNOR B. et al., "Peptide inhibition of glomerular deposition of an anti-DNA antibody"; PNAS, 1997, Vol. 94, pp 1955-60.	

Examiner		Date	
Signature	 	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	e for form 1449/PTO				Complete if Known
Qubsului	5 101 101111 1443/1 10			Application Number	10/574,994
INFO	ORMATION	I DIS	CLOSURE	Filing Date	October 5, 2004 (I.A.)
STA	TEMENT E	BY AI	PPLICANT	First Named Inventor	Betty A. Diamond
	(Use as many sh	oote se ne	ecessar/i	Art Unit	to be determined
	(OSE as many sin	ccis as ne	icessury)	Examiner Name	to be determined
Sheet	3	of	4	Attorney Docket Number	96700/1120

	<u> </u>	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	11	HANLY J.G. et al., "Brain Pathology in Systemic Lupus Erythematosus"; The Journal of Rheumatology, 1992, Vol. 19, No. 5, pp 732-41.	
	12	HUGHES G.R.V. et al., "The Anticardiolipin Syndrome"; The Journal of Rheumatology, 1986, Vol. 13, No. 3, pp 486-9.	
	13	JOHN G.R. et al., "Cytokines: Powerful Regulators of Glial Cell Activation"; The Neuroscientist, 2003, Vol. 9, No. 1, pp 10-22.	
	14	JONGEN P.J.H. et al., Cerebrospinal fluid C3 and C4 indexes in immunological disorders of the central nervous system"; Acta Neurologica Scandinavica, 2000, Vol. 101, No. 2, pp 116-21.	
	15	KAO C-H. et al., "The role of FDG-PET, HMPAO-SPET and MRI in the detection of brain involvement in patients with systemic lupus erythematosus"; European Journal of Nuclear Medicine, 1999, Vol. 26, No. 2, pp 129- 34.	
	16	KOZORA E. et al., "Magnetic Resonance Imaging Abnormalities and Cognitive Deficits in Systemic Lupus Erythematosus Patients Without Overt Central Nervous System Disease"; Arthritis & Rheumatism, 1998, Vol. 41, No. 1, pp 41-47.	
	17	LERITZ E. et al., "Neuropsychological Functioning and Its Relationship to Antiphospholipid Antibodies in Patients With Systemic Lupus Erythematosus"; Journal of Clinical and Experimental Neurophychology, 2002, Vol. 24, No. 4, pp 527-33.	
	18	LERITZ E. et al., "'Subcortical' cognitive impairment in patients with systemic lupus erythematosus"; Journal of the International Neuropsychological Society, 2000, Vol. 6, No. 7, pp 821-5.	
-	19	LIM M.K. et al., "Systemic Lupus Erythematosus: Brain MR Imaging and Single-Voxel Hydrogen 1 MR Spectroscopy"; Radiology, 2000, Vol. 217, No. 1, pp43-49.	
	20	NOMURA K. et al., "Asymptomatic Cerebrovascular Lesions Detected by Magnetic Resonance Imaging in Patients with Systemic Lupus Erythematosus Lacking a History of Neuropsychiatric Events"; Internal Medicine, 1999, Vol. 38, No. 10, pp 785-95.	

Examiner	Date	•	
Signature	Consid	ered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitut	e for form 1449/PTC)		Complete if Known		
				Application Number	10/574,994	
			CLOSURE	Filing Date	October 5, 2004 (I.A.)	
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Betty A. Diamond	
	(Use as many s	heets as ni	eressan/l	Art Unit	to be determined	
				Examiner Name	to be determined	
Sheet	4	of	4	Attorney Docket Number	96700/1120	

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	21	NYLÉN K. et al., "Cerebrospinal Fluid neurofilament and Glial Fibrillary Acidic Protein in Patients With Cerebral Vasculitis"; Journal of Neuroscience Research, 2002, Vol. 67, No. 6, pp 844-51.	
	22	PUTTERMAN C. and DIAMOND B., "Immunization with a Peptide Surrogate for Double-stranded DNA (dsDNA) Induces Autoantibody Production and Renal Immunoglobulin Deposition"; Journal of Experimental Medicine, 1998, Vol. 188, No. 1, pp 29-38.	
	23	SABET A. et al., "Neurometabolite Markers of Cerebral Injury in the Antiphospholipid Antibody Syndrome of Systemic Lupus Erythematosus"; Stroke, 1998, Vol. 29, No. 11, pp 2254-60.	
	24	SANNA G. et al., "Central nervous system involvement in systemic lupus erythematosis: cerebral imaging and serological profile in patients with and without overt neuropsychiatric manifestations"; Lupus, 2000, Vol. 9, No. 8, pp573-83.	
	25	SHARMA A. et al., "Studies of human polyclonal and monoclonal antibodies binding to lupus autoantigens and cross-reactive antigens"; Rheumatology, 2003, Vol. 42, pp 453-60.	
	26	SIBBITT, JR. W.L. et al., "Neuroimaging in Neuropsychiatric Systemic Lupus Erythematosus"; Arthritis & Rheumatism, 1999, Vol. 42, No. 10, pp 2026-38.	
	27	XAIO H. et al., "Effect of LPS on the permeability of the blood-brain barrier to insulin"; Brain Research, 2001, Vol. 896, No. 1,2, pp 36-42.	
	_		

Examiner	 	Date	
Signature		Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.